

**REMARKS**

This Amendment, submitted in response to the Office Action dated July 13, 2004, is believed to be fully responsive to each point of rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 6, 7 and 21-25 are all the claims pending in the application.

**I. Information Disclosure Statement**

The Examiner states that the Foreign Office Action dated September 24, 2003 in Form-1449 filed on April 29, 2004<sup>1</sup> has not been considered since an English translation was not provided. The references cited in the Japanese Office Action correspond to the U.S. Patents and Publication listed in the Form-1449 filed on June 22, 2004. It appears that all relevant information has been placed before the Examiner. In that connection, Applicant respectfully requests that the Examiner initial the PTO Form-1449 filed on June 22, 2004 and April 29, 2004.

**II. Claim Objections**

Claim 21 has been objected to because of the following informality: "the system" should be "the apparatus". Applicant has amended claim 21 as suggested by the Examiner. Consequently, the objection to claim 21 should be withdrawn.

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<sup>1</sup> Applicant respectfully brings to the Examiner's attention that the Form-1449 was filed on May 6, 2004 and not April 29, 2004.

### III. Claim Rejections under 35 U.S.C. § 102

Claims 6, 7, 21, 22 and 25 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Stimpson (U.S. Patent No. 6,037,186) as evidenced by Hayes et al. (U.S. Patent No. 4,877,745).

In response to Applicant's argument that Stimpson does not disclose the cutting means of claim 1, the Examiner asserts that Stimpson col. 12, second paragraph and col. 14, last paragraph teach the claimed cutting means.

Claim 1 recites "a cutting means which cuts the **sheet-like substrate** bearing thereon the plurality of specific binding agents in the first direction into a plurality of strips."

Column 12, lines 11-15 of Stimpson describe that cutting the rod or spiral bundles to form the arrays can be accomplished by using mechanical or laser methods. Razors or knife blades can be used to manually cut porous polymeric material to give arrays .2-1 mm thick. Column 14, lines 53-58 describe that a 1-2 mm length of the bundles was allowed to extend from the end of the metal tube and an array slab was cut with a razor blade using the metal tube as a guide to obtain a uniform straight cut. However, Stimpson does not disclose a sheet-like substrate, which is a structural limitation of claim 1, nor does Stimpson disclose a cutting means which cuts a sheet-like substrate into strips. The cutter disclosed in Stimpson cuts rod or spiral bundles. The orientation or method of cutting as described by claim 6 is not a necessary result in Stimpson.

The Examiner further asserts that the phrase “for manufacturing a test piece for use in biological analysis of a sample organism” is intended use (functional limitation) and not a structural limitation. However, a sheet-like substrate and a plurality of strips is further recited in the last two lines of claim 1. The sheet-like substrate and the plurality of strips are clearly structural elements.

Moreover, a functional limitation **must** be evaluated and considered just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. MPEP 2173.05. The disk form produced by Stimpson introduces an additional processing complexity that is avoided in Applicant’s invention.

Since the Examiner has not established where all of the structural and functional limitations of claim 6 are taught in the art, claim 6 and its dependent claims should be deemed patentable.

#### **IV. Claim Rejections under 35 U.S.C. § 103**

Claims 23 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Stimpson as evidenced by Hayes et al. and further in view of Shuminov (U.S. Patent No. 5,808,554).

In addressing Applicant’s arguments with respect to claims 23 and 24, the Examiner asserts that claim 6 only requires a plurality of applicators, a conveyor and a cutting means. Moreover, the Examiner asserts that claim 6 is not only directed to an apparatus that is only used in a biological field.

The preamble of claim 6 recites “An apparatus for manufacturing a test piece for use in **biological analysis** of a sample organism...” If the claim preamble, when read in the context of the entire claim, or, if the claim preamble is ‘necessary to give life, meaning and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim. MPEP 2111.02. In this case, the claim preamble clearly gives life and meaning to the claim for example, the provision of deposits of specific binding agents would indicate the non-applicability of the Shuminov diaper patent. The purpose of an exemplary embodiment of the present invention is for DNA or immunological analysis. See Abstract.

Moreover, the Examiner asserts that although Shuminov’s patent is not from a biological field, Shuminov’s patent is considered analogous art because both Stimpson and Shuminov teach a conveyor. However, merely because both references teach a conveyor does not mean that the references teach the conveyor as claimed. The Examiner cannot randomly pick and choose elements of the prior art to teach the claimed elements when there is clearly no motivation or suggestion for the combination. The mere presence of a purportedly similar structure in disparate art does not justify a combination when the goals and purposes of each are not related. *A.J. Deer Co. v. U.S. Slicing Mach. Co.*, 21 F.2d 812, 813 (7<sup>th</sup> Cir. 1927). The Examiner’s reasoning is clearly a result of impermissible hindsight.

In addition, the references are not analogous merely because both references teach a conveyor. In order to rely on a reference as a basis for rejection of an applicant’s invention, the reference must either be in the field of applicant’s endeavor or, if not, then be **reasonably** pertinent to the particular problem with which the inventor was concerned. MPEP 2141.01(a).

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Shuminov is clearly not in the same field of endeavor as the applicant's invention nor does Shuminov attempt to provide a method and system for reading a test piece and improve the sequence of specific binding agents on a test piece, as described in an exemplary embodiment of the present invention.

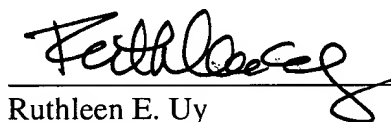
For at least these reasons, claims 23 and 24 should be deemed patentable.

**V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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